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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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08/888,202 07/07/97 PIMENTEL

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EXAMINER

UNGAR, S

ART UNIT

PAPER NUMBER

1642

13

DATE MAILED:

10/26/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
08/888,202

Applicant(s)
Pimentel

Examiner
Ungar

Group Art Unit
1642



☒ Responsive to communication(s) filed on Aug 9, 1999

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-3, 8, 14, 17-22, and 25-37 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 8, 14, 17-22, and 25-37 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 9

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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1. The request filed on August 2, 1999 (Paper No. 10) for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 08/888,202 is acceptable and a CPA has been established. An action on the CPA follows.

2. Previously pending claim 4 has been canceled, claims 1-3, 8, and 34 have been amended and new claims 36-37 have been added. Claims 1-3, 8, 11, 17-22 and 25-37 are pending and currently under examination.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The following rejections are being maintained:

Claim Rejections - 35 USC § 103

5. Claims 1-3, 8, 11, 14 and 17-22 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 8, Section 5, pages 2-3 and Paper No. 5, Section 9, pages 4-8 and claims 25-35 remain rejected for the reasons previously set forth in Paper No. 8, Sections 7 and 8, pages 4-7.

Applicant argues that (a) without any suggestion to combine the teachings of the references in the manner proposed by the Examiner, it should not be the case that the combination of all of the cited references make up the state of the art with regard to the claimed invention, (b) the Atkinson Affidavit demonstrates that many of the references are from non-analogous art to one another as well as to the claimed invention and one of ordinary skill in the art would not have looked to all of the references if faced by the problem presented by the applicant. The arguments have been noted but have not been found persuasive because (a) the test for obviousness

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is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981), (b) the Atkinson Affidavit is not persuasive for the reasons set forth below.

The Atkinson Affidavit (a) discusses the problem of obesity, (b) specifically states "That antibodies can reach the duodenum and still be active to inhibit pancreatic lipase was not obvious to me as of July 7, 1997.", (c) admits on the record that tetrahydroloprostatin, although a different molecule than an antibody, successfully blocks pancreatic lipase *in vivo*, (d) states that the references cited by Examiner drawn to the 35 USC 103 rejections relate to non-analogous art and would not be combined in the manner proposed by Examiner, (e) goes on to specify the specific art represented by each of the references and to explain that if a reference is in one art which is nonanalogous to another art it would not be looked to by one of skill in the art seeking to solve a particular problem, (f) argues the references individually. The affidavit is not persuasive because (a) although the discussion of obesity is noted, it does not appear to be relevant to the instant rejection (b) it is was conventional in the art, at the time the invention was made, to orally administer antibodies to animals for intestinal treatments and it is clear from the art that the orally administered antibodies retained activity. For example, US Patent No. 5,753,228, although drawn to a method of treating intestinal parasitosis by the enteral administration of antibodies (see abstract) clearly claims enteral

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administration, that is by oral ingestion, gastric intubation, rectal intubation or the direct injection of antibodies into the intestinal tract of a mammal (claim 3) and exemplifies the successful enteral passive immunization of neonatal mice (col 9), further, the Patent specifically cites a number of references drawn to the successful oral administration of antibodies in piglets and humans for intestinal protocols (see col 2). Further, Perryman et al (Infection and Immunity, 1993, 61:4906-4908) teach the effective oral administration of antibody for intestinal protocols in scid mouse (see abstract) and Martin et al (Am. J. Physiol., 1994, 266:G417-G424) teach the effective oral administration of antibody for intestinal protocols in rats and specifically report that the orally administered antibodies retained their neutralizing capabilities (see abstract), thus, it would have been expected by one of skill in the art that orally administered anti-lipase activity would be retained in the gastrointestinal tract, (c) the rejections are based on the known efficacy of an anti-lipase activity in combination with the known effects of anti-lipase antibodies and the known efficacy of oral administration of antibodies, (d) the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference and it is not that the claimed invention must be expressly suggested in any one or all of the references; but rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981), (e) the expressed opinion is not supported by objective evidence, (f) Applicant has argued and discussed the references individually without clearly addressing the combined teachings. It must be remembered that the references are relied upon in combination

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and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Applicant's arguments have not been found persuasive and the rejection is maintained.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

6. Claims 36 and 37 are rejected under 35 USC 103 as being unpatentable over US Patent No. 4,598,089 in view of Moloney, Flint, Ohkaru et al or JP 02150294, US Patent No. 5,585,098, US Patent No. 5,080,895 as drawn to claims 1-3, 8, 11, 14 and 17-22 and further in view of Martin et al, *Supra*, US Patent No. 5,753,228, *Supra* and Perryman et al, *Supra*.

The claims are drawn to a method for inhibiting lipase in a non-ruminant mammal by introducing an antibody into the lower gastro-intestinal tract of the non-ruminant mammal through the digestive system of the non-ruminant mammal wherein said antibody is introduced into the digestive system by oral feeding in a capsule that protects said antibody until it reaches said lower gastro-intestinal tract.

US Patent No. 4,598,089, Moloney, Flint, Ohkaru et al or JP 02150294, US Patent No. 5,585,098, US Patent No. 5,080,895 teach as set forth above but the combined references do not teach oral administration of an antibody for inhibiting lipase in a non-ruminant mammal or encapsulation of said antibody.

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Martin et al, *Supra*, US Patent No. 5,753,228, *Supra* and Perryman et al, *Supra* teach as set forth above.

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, and one would have been motivated at the time the invention was made, to orally administer an anti-lipase antibody to a mammal for the reasons previously set forth in Paper Nos 5 and 8. Further, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to orally administer an anti-lipase antibody to a non-ruminant mammal in order to further characterize the actions of said antibody in an animal model as demonstrated by the characterization of the antibodies of Martin et al, US Patent No. 5,753,228 and Perryman et al with a reasonable expectation of success as orally administered antibodies clearly retain their functional capabilities. Finally it would have been *prima facie* obvious and one of ordinary skill in the art would have been motivated, at the time the invention was made, to encapsulate the antibody in order to optimize delivery of the antibody to the GI-tract.

9. No claims allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Paula Hutzell, can be reached at (703) 308-4310. The fax phone number for this Art Unit is (703) 308-4242.

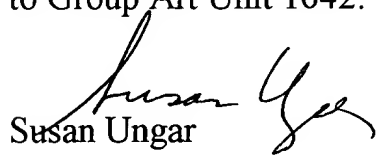
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.


Susan Ungar

October 20, 1999

Primary
SUSAN UNGAR
PATENT EXAMINER